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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. <i>20</i>
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EXAMINER

ART UNIT	PAPER NUMBER <i>12</i>
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DATE MAILED: ,

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/423,622

Applicant(s)

MULLER ET AL.

Examiner

Bridget E. Bunner

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1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 18-35 is/are pending in the application.
- 4a) Of the above claim(s) 30-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 18-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims 18-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment filed 08 March 2001 (Paper No. 11) has been entered. Claims 1-17 are cancelled and claims 18-35 are added.

Newly submitted claims 30-35 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 30-35 are directed to a non-elected group that was previously restricted in Paper No. 7 (08 August 2000).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 30-35 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 18-29 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections and/or Rejections

1. The objection to the specification as set forth at pg 2-4 of the previous Office Action (Paper No. 9, 08 November 2000) is *withdrawn in part* in view of the amended sentences of the specification (Paper No. 11, 08 March 2001). Please see section on Specification, below.
2. The rejections to claims 10-14 under 35 USC § 101 as set forth at pg 5 of the previous Office Action (Paper No. 9, 08 November 2000) are *withdrawn* in view of the cancelled and newly submitted claims (Paper No. 11, 08 March 2001).

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3. The rejections to claims 1-14 as set forth at pg 9-11 of the previous Office Action (Paper No. 9, 08 November 2000) are *withdrawn in part* in view of the cancelled and newly submitted claims (Paper No. 11, 08 March 2001). Please see section on 35 U.S.C. § 112, second paragraph, below.

4. The rejections to claims 1 and 6 as set forth at pg 12 of the previous Office Action (Paper No. 9, 08 November 2000) are *withdrawn* in view of Applicant's convincing arguments (Paper No. 11, 08 March 2001).

Specification

5. The disclosure is objected to because of the following informalities:

5a. Applicant argues (pg 9, Paper No. 11, 08 March 2001) that the revised specification addresses the objections set forth at pg 3-4 of the previous Office Action (Paper No. 9, 08 November 2000). Applicant's arguments have been fully considered but are not found to be persuasive because the specification still has no section headings.

5b. Applicant amended the first sentence on page 12, line 5 in Paper No. 11 (08 March 2001) and upon doing so, changed "slices of 400 μ m thickness" to incorrectly state "slices of 400 m thickness".

Appropriate correction is required.

Claim Objections

6. Applicant argues (pg 9, Paper No. 11, 08 March 2001) that the language used in the new claims addresses the objections set forth at pg 4-5 of the previous Office Action (Paper No. 9, 08 November 2000). Applicant's arguments have been fully considered but are not found to be persuasive because claim 23 is still objected to under 37 CFR 1.75(c), as being of improper

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dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112, first paragraph

7. Claims 18-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for enhancing fornix axonal regeneration by administering a basal membrane inhibitor, more specifically an iron chelator, to injured neuronal tissue, does not reasonably provide enablement for generically improving neuronal regeneration comprising prevention or inhibition of basal membrane formation induced by a lesion of neuronal tissue. The basis for this rejection is set forth in the rejection of claims 1-14, now cancelled, at pg 6-9 of the previous Office Action (Paper No. 9, 08 November 2000).

Applicant's arguments (pg 10-12, Paper No. 11, 08 March 2001) have been fully considered but are not found to be persuasive for the following reasons:

Applicant cites case law and PTO guidelines to attempt to establish that the invention in the instant application is enabled under 35 U.S.C. § 112, first paragraph. Applicant asserts that any improvement in neural regeneration achieved by the present invention is sufficient to satisfy enablement of "using" under § 112, first paragraph. Further, Applicant states that Jackowski teaches nothing inconsistent with the utility of improving neural regeneration by inhibiting basal membrane formation induced by a lesion of the neural tissue, claimed in the present invention. This has been fully considered but not found to be persuasive because Applicant has not provided evidence to demonstrate that Jackowski teaches nothing inconsistent with the proposed utility of the instant application. Jackowski was relied upon to establish that

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regeneration does not occur in the CNS, which is an embodiment upon which the claims read. As discussed in detail in the previous Office Action (Paper NO. 9, 08 November 2000), the specification fails to teach the skilled artisan how to practice the claimed methods in their full scope. Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to improve neuronal regeneration comprising prevention or inhibition of basal membrane formation induced by a lesion of neuronal tissue, the lack of direction/guidance presented in the specification regarding the "prevention" of basal membrane formation, when the inhibitor substance should be stopped or slowed, and how to rescue dead and dying cells, the absence of working examples directed to prevention or inhibition of scar formation of the spinal cord, the complex nature of the invention, the unpredictability of axon regeneration, and the breadth of the claims which fail to recite limitations on the region of the CNS affected and the type of neuronal cells that sprout axons, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

35 USC § 112, second paragraph

Claims 18, 23, and 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 18 provides for the use of a method for the improvement of neuronal regeneration by prevention or inhibition of basal membrane formation, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active,

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positive steps delimiting how this use is actually practiced. The basis for this rejection is set forth in the rejection of claim 1, now cancelled, at pg 9 of the previous Office Action (Paper No. 9, 08 November 2000).

9. Claim 23 is rejected as being indefinite because a claim that depends from a claim which recites elements or steps with closed claim language cannot add an element or step. The transitional phrase "is" in claims 21 and 23 is interpreted to be closed claim language. The basis for this rejection is set forth in the rejection of claims 5 and 14, now cancelled, at pg 9 of the previous Office Action (Paper No. 9, 08 November 2000).

10. Claims 25-29 are rejected as being indefinite because the claims do not resolve the 35 U.S.C. 112, second paragraph, issues of claim 18.

Applicant argues (pg 12-13, Paper No. 11, 08 March 2001) that the language in the new claims resolves the issues raised in the 35 USC § 112, second paragraph statement of rejection of the previous Office Action (Paper No. 9, 08 November 2001). Applicant's arguments have been fully considered but are not found to be persuasive because the claims still have 35 USC § 112, second paragraph issues as discussed above.

Claim Rejections - 35 USC § 102

11. Claims 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Logan et al. (WO 93/19783). The basis for this rejection is set forth in the rejection of claims 1-3 and 10-12, now cancelled, at pg 11-12 of the previous Office Action (Paper No. 9, 08 November 2000).

Applicant's arguments (Paper No. 11, 08 March 2001), as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

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Applicant argues that Logan et al. discloses use of a non-specific agent, TGF- β , and therefore, cannot anticipate the invention in the instant application because a method is claimed for the improvement of neuronal regeneration by "specific inhibition" of basal membrane formation. Applicant asserts that Logan et al. does not relate to the production of an extracellular matrix in the central nervous system with the basal membrane. Applicant's arguments have been fully considered but they are not persuasive. Many biological molecules have several "specific" functions. However, a "specific" function does not necessarily mean that it is a unique function. Further, Applicants do not support the assertion that "specific" inhibition of the basal membrane means "unique" inhibition with any evidence. Logan et al. teaches a method of improving neuronal regeneration comprising administering an inhibitor of TGF- β , which ultimately inhibits collagen IV and basal membrane formation. Therefore, Logan et al. teaches all of the limitations of claims 18-20.

Claim Rejections - 35 USC § 103

12. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Logan et al. (WO 93/19783) in view of White and Kraus (Annals of Emergency Med. 22:970-979) and Kivirikko et al (FASEB J. 3:1609-1617). The basis for this rejection is set forth in the rejection of claims 4-5 and 13-14, now cancelled, at pg 13-15 of the previous Office Action (Paper No. 9, 08 November 2000).

Applicant's arguments (Paper No. 11, 08 March 2001), as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant argues that White and Kraus are not related to the field of the presently claimed invention and that White and Kraus and Kivirikko et al. do not construct any relation to

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the basal membrane. Applicant states that the reference teaches to avoid brain lesions by manipulation into the basic metabolism to avoid destruction of the cell membrane by administration of iron chelators. Applicant suggests that the object of this reference is to avoid cell damage rather than to regenerate nerves. Further, Applicant states that the person of ordinary skill in the art would not have been motivated to combine the teachings of the different references.

Applicant's arguments have been fully considered but they are not persuasive. Specifically, Logan et al. teaches a method for the prevention, suppression, or treatment of a central nervous system (CNS) pathology, such as scar formation, characterized by accumulation of extracellular matrix in a tissue by contacting the tissue with an agent that inhibits the extracellular matrix producing activity of TGF- β (pg 1-4). TGF- β stimulates the synthesis of fibronectin and collagen and blocks matrix degradation (pg 4, lines 28-35). One skilled in the art at the time the invention was made would know that one of the components of the extracellular matrix is the basal membrane, which is composed of such elements as collagen IV, laminin, and entactin (pg 2 of the instant specification). White and Krause and Kivirikko et al. teach other compounds, such as iron chelating agents, that inhibit the enzyme responsible for collagen accumulation and therefore it would have been obvious to use these same compounds to inhibit the formation of the extracellular matrix (as taught by Logan et al.) and in turn the basal membrane.

Further, in response to applicant's arguments, the recitation "for the improvement of nerve regeneration" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites

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the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In response to applicant's argument that the person of ordinary skill in the art would not have been motivated to combine the teachings of the different references, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bridget E. Bunner
Art Unit 1647
May 3, 2001

Elyabeth C. Kemm

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MAY 10 2001